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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,435	10/16/2003	Geert Maertens	2551-130	5780

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NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/685,435

Applicant(s)

MAERTENS ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-25 and 28-59 is/are pending in the application.
- 4a) Of the above claim(s) 28,30,31,49-56,58 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23- 25, 29, 32-48, and 57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 23-25, and 28-59 are pending in the present application. In the prior action, mailed on December 30, 2004, claims 24, 25, 29, and 32-48 were rejected; claim 23 was objected to; and claims 28, 30, 31, and 49-56 were withdrawn from consideration. In the Response of May 5, 2005, the Applicant added new claims 57-59. New claims 58 and 59 are drawn to non-elected inventions, and are therefore withdrawn from examination.
2. Currently, claims 23-25, 29, and 32-48, and new claim 57 are under consideration.
3. Because this action raised new grounds of rejection not previously made (i.e. the inclusion of claim 23 in the obviousness rejection) the action is made Non-Final.

### *Sequence Listing*

4. **(Prior Objection-Withdrawn)** The specification was objected to for referring to protein or nucleic acid sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). See e.g., page 22, line 21; and page 25, lines 12 and 20. Applicant traverses the objection on the basis that the specification was amended to include such identifiers in the Preliminary Amendment of October 16, 2003. The corrections are acknowledged and the objection is withdrawn.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **(Prior Rejection-Withdrawn)** Claims 24, 28, 29, 32-48 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As indicated in the prior action, the claim is being read as reading on any peptide of up to 45 residues that comprise

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some sequence that may be found within SEQ ID NO: 15. The “consisting of” language is read as excluding peptides of greater than 45 residues in length. Because this language clearly, albeit broadly, defines the invention, the rejection is withdrawn.

7. **(Prior Rejection- Maintained)** Claim 29 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant traverses this rejection on the basis that similar claims were allowed by the present Examiner in prior application 09/5662666 (now patent 6,855,318). This argument is not found persuasive because the Examiner did not in fact allow the indicated claim language. In particular, it is noted that an Examiner’s amendment, mailed on July 28, 2004, and approved by the current representative of Applicant, was made in which the phrase “anti-HCV-related” was deleted and replaced with “anti-HCV.” The Applicant’s arguments are therefore not found persuasive, and the rejection is maintained.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **(Prior Rejection- Maintained)** Claim 29 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for kits comprising peptides of SEQ ID NO: 15 for the detection of anti-HCV antibodies, does not reasonably provide enablement for kits comprising this peptide for the detection of any “HCV-related virus.” In traversal of the rejection, the Applicant points to Patent 6,855,318, issued by the current Examiner. The claims

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of this patent describe, as asserted by the Applicant, anti-HCV related antibodies. However, a reading of the prosecution history for the application from which the patent was issued would indicate that the claims published in the patent were not up to date with all the amendments in the application. In particular, an Examiner's amendment, mailed on July 28, 2004, and approved by the current representative of Applicant, was made in which the phrase "anti-HCV-related" was deleted and replaced with "anti-HCV." The Applicant's arguments are therefore not found persuasive, and the rejection is maintained.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. **(Prior Rejection- Maintained in part)** Claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46, and 47 were rejected under 35 U.S.C. 102(b) as being anticipated by Maertens et al. (WO 96/04385- of record in the October 2003 IDS). The rejection is withdrawn from claim 25, and extended to new claim 57.

The Applicant traverses the rejection on the basis that none of the peptides of Maertens include the full-length peptide of SEQ ID NO: 15. However, claim 24 does not, as asserted by

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the Applicant, require the full-length peptide of SEQ ID NO: 15. Rather, the claim reads on a peptide of up to 45 amino acids "wherein an amino acid sequence selected from SEQ ID NOs: 1-16 and 37 is present in said peptide. As indicated in the prior action (page 5, carryover from paragraph 7), this language is read so as to include any amino acid sequence that may be found in the indicated sequences (currently, SEQ ID NO: 15), including both the entirety of that sequence and portions thereof.

With respect to claim 57, it is noted that the claim requires only the presence of the peptide, the other elements being optional. Thus, the reference anticipates this claim. However, it is further noted that the reference additionally teaches kits for the detection of HCV antibodies in a sample comprising the peptides disclosed therein, a solid substrate, and a detectable moiety (i.e. a marker according to claim 57). The reference would therefore also either anticipate or render obvious the claim even were the additional elements to be mandatory rather than optional.

However, because the reference does not teach a peptide comprising between 21 and 33 residues of SEQ ID NO: 15, the rejection is withdrawn from claim 25.

Because the Maertens reference teaches peptides including portions of SEQ ID NO: 15, and such peptides are less than 45 residues in length, the rejection is maintained against pending claims 24, 29, 32-34, 36, 38, 40, 41, 43-47, and is extended to new claim 57, for the reasons above, and the reasons of record.

12. **(Prior Rejection- Maintained)** Claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Dreesman et al. (WO 93/06488- of record in the October 2003 IDS). As noted by the Applicant, the cited reference

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teaches a peptide sharing only 11 residues with SEQ ID NO: 15. As such is insufficient to maintain the rejection against claim 25, the rejection of this claim is withdrawn. However, the rejection is maintained with respect to claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46, and 47. Further, the rejection is extended to new claim 57. The Applicant's arguments in traversal of the rejection are noted. These arguments are substantially the same as asserted with respect to the Maertens reference above. For the reasons above, these arguments are not found persuasive. The rejection is therefore maintained for these reasons, and for the reasons of record.

With respect to claim 57, it is noted that the reference also teaches the use of the peptides in methods for the detection of anti-HCV antibodies. Pages 11-13 The reference would therefore also either anticipate or render obvious the claim even were the additional elements to be mandatory rather than optional.

The rejection is therefore maintained against claims 24, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46, and 47, and extended to claim 57, for the reasons above, and the reasons of record.

13. **(Prior Rejection- Maintained)** Claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (U.S. Patent 5,747,239- of record in the October 2003 IDS). The claims have been described above. Because claim 25 is limited to peptides of 21 to 33 contiguous amino acids from SEQ ID NO: 15, the rejection is withdrawn from this claim. However, for the reasons indicated above with respect to the Maertens and Dreesman references, the rejection is maintained over claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46, and 47, and extended to claim 57.

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14. **(Prior Rejection- Maintained)** Claims 24, 29, and 32-48 are rejected under 35 U.S.C. 102(e) as being anticipated by the '503 Patent (U.S. Patent 6,245,503, issued to Maertens et al.). The claims have been described above. As indicated in the prior action, this reference teaches the same peptides as disclosed in the Maertens reference above. The Applicant traverses the rejection on substantially the same grounds as argues with respect to that reference. The arguments are not found persuasive for the same reasons as were indicated with respect to that rejection. Therefore, for the reasons above and the reasons of record, the rejection is maintained against claims 24, 29, and 32-48, and is extended to new claim 57.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. **(Prior Rejection- Reformed and Maintained)** Claims 24, 25, 29, 32-34, 36, 38, 40, 41, and 43-47 were rejected under 35 U.S.C. 103(a) as being unpatentable over Maertens et al. (WO 96/04385), and further in view of either of Choo et al. (PNAS 88: 2451-55) or Zonara et al. (J Hepatol 21: 858-65). The Applicant makes a blanket assertion that the secondary references fail to cure the deficiencies of the primary reference as asserted with respect to the rejection under 35 U.S.C. 102. The argument is not found persuasive with respect to claims 24, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46, and 47. Further, the Applicant's arguments in traversal make no attempt to



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address the teachings of the reference rendering the peptides of claims 25 obvious. The rejection is therefore maintained for the reasons of record.

Additionally, because the references render obvious HCV peptides comprising fragments of E1 protein corresponding to those disclosed by the Maertens reference, the combination also renders obvious the peptide of claim 23.

The rejection is extended to new claim 57 for substantially the same reasons as indicated with respect to the anticipation rejections above.

17. **(Prior Rejection- Maintained)** Claims 35, 37, 39, 42, 45, and 48 were rejected under 35 U.S.C. 103(a) as being unpatentable over any of Dreesman, Wang, or Maertens in view of Choo as applied above, and further in view of De Leys et al. (WO 93/18054). As with the obvious rejection above, the Applicant's only argument in traversal is a blanket assertion that the secondary references fail to cure the deficiencies of the primary references. As this argument is not found persuasive for the reasons indicated above, the rejection is maintained.

### ***Conclusion***


18. No claims are allowed.


19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Z. Lucas  
Patent Examiner

  
JAMES HOUSEL 7/11/05  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600